

In the Claims

Please replace all prior versions, and listings, of claims in the application with the following list of claims:

1. (Currently Amended) A method for producing a therapeutic effect, comprising: administering to a pulmonary tissue of a subject an ~~unformulated dry polysaccharide~~ a heparin-like glycosaminoglycan particle in an amount for producing a therapeutic effect, wherein the ~~unformulated dry polysaccharide~~ heparin-like glycosaminoglycan particle has a mean geometric diameter of 1-500 microns, and wherein the ~~unformulated dry polysaccharide~~ heparin-like glycosaminoglycan is a therapeutic polysaccharide.
2. (Canceled)
3. (Currently Amended) The method of claim [[2]] 1, wherein the heparin-like glycosaminoglycan is a heparin.
4. (Currently Amended) The method of claim [[2]] 1, wherein the heparin-like glycosaminoglycan is a heparin sulfate.
5. (Currently Amended) The method of claim [[2]] 1, wherein the heparin-like glycosaminoglycan is a low molecular weight heparin.
- 6-10. (Canceled)
11. (Currently Amended) The method of claim 1, wherein the ~~unformulated dry polysaccharide~~ heparin-like glycosaminoglycan particle has a mean geometric diameter of 1-200 microns.

12. (Currently Amended) The method of claim 1, wherein the unformulated dry polysaccharide heparin-like glycosaminoglycan particle has a mean geometric diameter of 1-53 microns.

13. (Currently Amended) The method of claim 1, wherein the unformulated dry polysaccharide heparin-like glycosaminoglycan particle has a mean geometric diameter of 53-106 microns.

14. (Currently Amended) The method of claim 1, wherein the unformulated dry polysaccharide heparin-like glycosaminoglycan particle has a mean geometric diameter of 1-5 microns.

15. (Currently Amended) The method of claim 1, wherein the unformulated dry polysaccharide heparin-like glycosaminoglycan particle has a mean aerodynamic diameter of 1-5 microns.

16. (Currently Amended) The method of claim 1, wherein the unformulated dry polysaccharide heparin-like glycosaminoglycan particle has a mean aerodynamic diameter selected from the group consisting of 5-35 and 35-75 microns.

17. (Currently Amended) The method of claim [[2]] 1, wherein the subject has a coagulation disorder and the therapeutic effect of the heparin-like glycosaminoglycan is anti-coagulation or antithrombosis.

18. (Original) The method of claim 17, wherein the coagulation disorder is selected from the group consisting of thrombosis associated with cardiovascular disease and vascular conditions.

19. (Original) The method of claim 18, wherein the cardiovascular disease is selected from the group consisting of acute myocardial infarction, unstable angina, and atrial fibrillation.

20. (Original) The method of claim 18, wherein the vascular condition is selected from the group consisting of deep venous thrombosis, stroke, and pulmonary embolism.

21. (Currently Amended) The method of claim 17, wherein the heparin-like glycosaminoglycan is administered in an amount effective to produce a minimum therapeutic level of approximately 0.2 IU/ml anti-factor Xa activity.

22. (Currently Amended) The method of claim [[2]] 1, wherein the subject is preparing to undergo, is undergoing or is recovering from a surgical procedure.

23. (Original) The method of claim 22, wherein the surgical procedure is selected from the group consisting of cardiac-pulmonary by-pass surgery, coronary revascularization surgery, orthopedic surgery, and prosthesis replacement surgery.

24. (Currently Amended) The method of claim [[2]] 1, wherein the subject has atherosclerosis.

25. (Currently Amended) The method of claim [[2]] 1, wherein the subject has a respiratory disorder.

26. (Original) The method of claim 25, wherein the respiratory disorder is selected from the group consisting of asthma, emphysema, adult respiratory distress syndrome (ARDS), and lung reperfusion injury.

27. (Currently Amended) The method of claim [[2]] 1, wherein the subject has a cancer or metastasis.

28. (Currently Amended) The method of claim [[2]] 1, wherein the subject has an inflammatory disorder.

29. (Currently Amended) The method of claim [[2]] 1, wherein the subject has an allergy.

30. (Currently Amended) The method of claim [[2]] 1, wherein the subject has an angiogenic disorder and the heparin-like glycosaminoglycan is administered in an effective amount for preventing angiogenesis.

31. (Previously Presented) The method of claim 30, wherein the angiogenic disorder is selected from the group consisting of neovascular disorders of the eye, osteoporosis, psoriasis, and arthritis.

32. (Canceled)

33. (Currently Amended) The method of claim 1, wherein the unformulated dry polysaccharide heparin-like glycosaminoglycan is self administered by the subject.

34. (Currently Amended) The method of claim 1, wherein the unformulated dry polysaccharide heparin-like glycosaminoglycan is administered through a tracheal tube.

35. (Currently Amended) The method of claim [[2]] 1, wherein the subject is undergoing a tissue or organ transplant.

36. (Currently Amended) The method of claim 1, wherein the unformulated dry polysaccharide heparin-like glycosaminoglycan has a tap density of 0.01 - 0.4 g/cm³.

37. (Currently Amended) The method of claim 1, wherein the unformulated dry polysaccharide heparin-like glycosaminoglycan has a tap density of greater than 0.4 g/cm³.

38. (Currently Amended) A method for delivering at least 5% of a therapeutic polysaccharide to lower respiratory tract, comprising:

administering to a pulmonary tissue of a subject ~~an unformulated dry polysaccharide a heparin-like glycosaminoglycan~~ particle, wherein the ~~unformulated dry polysaccharide heparin-like glycosaminoglycan~~ particle has a mean geometric diameter of 1-500 microns, and wherein at least 5% of the ~~polysaccharide heparin-like glycosaminoglycan~~ administered is delivered to the lower respiratory tract, and wherein the ~~polysaccharide heparin-like glycosaminoglycan~~ is a therapeutic polysaccharide.

39-41. (Canceled)

42. (Currently Amended) A method for systemically delivering a therapeutic polysaccharide to a subject, comprising:

administering to a pulmonary tissue of the subject ~~an unformulated dry polysaccharide a heparin-like glycosaminoglycan~~ particle, wherein the ~~unformulated dry polysaccharide heparin-like glycosaminoglycan~~ particle has a mean geometric diameter of 1-500 microns, and wherein the ~~unformulated dry polysaccharide heparin-like glycosaminoglycan~~ particle is delivered systemically, and wherein the ~~unformulated dry polysaccharide heparin-like glycosaminoglycan~~ is a therapeutic polysaccharide.

43. (Previously Presented) An unformulated dry heparin-like glycosaminoglycan having a mean geometric diameter of 1-500 microns.

44-57. (Canceled)

58. (Previously Presented) A method for delivering a heparin-like glycosaminoglycan to a subject, comprising, administering to a pulmonary tissue of a subject the heparin-like glycosaminoglycan of claim 43.

59. (Currently Amended) A method of delivering a therapeutic polysaccharide to a subject comprising:

administering a dry aerosol containing a therapeutic polysaccharide to a pulmonary tissue of a subject in an effective amount to produce a peak plasma concentration of therapeutic

polysaccharide within two hours, wherein the therapeutic polysaccharide is a heparin-like glycosaminoglycan.

60-72. (Canceled)

73. (Currently Amended) A method of delivering a therapeutic polysaccharide to a subject comprising:

administering a dry aerosol containing a therapeutic polysaccharide to a pulmonary tissue of a subject in an effective amount to deliver at least 5% of the therapeutic polysaccharide to the blood within one hour, wherein the therapeutic polysaccharide is a heparin-like glycosaminoglycan.

74-78. (Canceled)

79. (Currently Amended) A method for producing a therapeutic effect, comprising:
administering a dry aerosol containing a therapeutic polysaccharide to a pulmonary tissue of a subject in an effective amount for producing a therapeutic effect within 1 hour of administration, wherein the therapeutic polysaccharide is a heparin-like glycosaminoglycan.

80-81. (Canceled)

82. (Original) A composition comprising a dry aerosol formulation of particles containing a heparin-like glycosaminoglycan, wherein the particles have a mean geometric diameter of greater than 30 microns.

83-88. (Canceled)

89. (Original) A composition comprising a dry aerosol formulation of particles containing a heparin-like glycosaminoglycan, wherein the particles have a mean aerodynamic diameter of greater than 5 microns.

90. (Original) A composition comprising a dry aerosol formulation of particles containing a heparin-like glycosaminoglycan, wherein the particles have a tap density of greater than 0.4 g/cm³.

91. (Currently Amended) A kit for administering a dry aerosol containing a polysaccharide heparin-like glycosaminoglycan to the respiratory tract of a subject comprising:
an inhalation apparatus,
polysaccharide heparin-like glycosaminoglycan dry aerosol particle formulation, wherein the polysaccharide heparin-like glycosaminoglycan dry aerosol particle is formulated to release at least 5% of the polysaccharide heparin-like glycosaminoglycan within 2 hours and
a detection system to determine the level of the polysaccharide heparin-like glycosaminoglycan administered.

92-98. (Canceled)

99. (Original) A method for delivering a polysaccharide to a subject, comprising:
administering to a pulmonary tissue of the subject a dry aerosol formulation comprising an unformulated dry glycosaminoglycan preparation and a formulated dry glycosaminoglycan preparation to deliver the polysaccharide to the subject.

100-112. (Canceled)

113. (Currently Amended) The method of claim 38, wherein at least 10% of the therapeutic polysaccharide heparin-like glycosaminoglycan administered is delivered to the lower respiratory tract.

114. (Currently Amended) The method of claim 38, wherein at least 30% of the therapeutic polysaccharide heparin-like glycosaminoglycan administered is delivered to the lower respiratory tract.

115. (Currently Amended) The method of claim 38, wherein at least 50% of the therapeutic polysaccharide heparin-like glycosaminoglycan administered is delivered to the lower respiratory tract.

116. (Previously Presented) The unformulated dry heparin-like glycosaminoglycan of claim 43, wherein the unformulated dry heparin-like glycosaminoglycan has a mean geometric diameter of 1-200 microns.

117. (Previously Presented) The unformulated dry heparin-like glycosaminoglycan of claim 43, wherein the unformulated dry heparin-like glycosaminoglycan has a mean geometric diameter of 1-53 microns.

118. (Previously Presented) The unformulated dry heparin-like glycosaminoglycan of claim 43, wherein the unformulated dry heparin-like glycosaminoglycan has a mean geometric diameter of 1-5 microns.

119. (Previously Presented) The unformulated dry heparin-like glycosaminoglycan of claim 43, wherein the unformulated dry heparin-like glycosaminoglycan has a mean geometric diameter of 5-53 microns.

120. (Previously Presented) The unformulated dry heparin-like glycosaminoglycan of claim 43, wherein the unformulated dry heparin-like glycosaminoglycan has a mean geometric diameter of 53-106 microns.

121. (Currently Amended) The unformulated dry heparin-like glycosaminoglycan of claim 43, wherein the heparin-like glycosaminoglycan is selected from the group consisting of a heparin, a heparin sulfate, or a low molecular weight heparin, a biotechnology derived heparin, a chemically modified heparin, a heparin analogue, and an unfractionated heparin preparation.

122. (Previously Presented) A composition, comprising:
the unformulated dry heparin-like glycosaminoglycan of claim 43 and a formulated dry glycosaminoglycan preparation.

123. (Currently Amended) The composition of claim 122, wherein the glycosaminoglycan of the formulated dry glycosaminoglycan preparation is ~~selected from the group consisting of~~ a heparin, a heparin sulfate, or a low molecular weight heparin, ~~a biotechnology derived heparin, a chemically modified heparin, a heparin analogue, and an unfractionated heparin preparation.~~

124. (Previously Presented) The composition of claim 122, wherein the glycosaminoglycan of the formulated dry glycosaminoglycan preparation is the same as the glycosaminoglycan of the unformulated dry heparin-like glycosaminoglycan preparation.

125. (Previously Presented) The composition of claim 122, wherein the glycosaminoglycan of the formulated dry glycosaminoglycan preparation is different than the glycosaminoglycan of the unformulated dry heparin-like glycosaminoglycan preparation.

126. (Canceled)

127. (Currently Amended) The composition of claim [[126]] 122, wherein the ~~polymer is selected from the group consisting of~~ formulated dry glycosaminoglycan preparation includes PLA, PGA, and or PLGA.

128. (Previously Presented) The composition of claim 122, wherein the formulated dry glycosaminoglycan preparation includes a surfactant.

129. (Previously Presented) The composition of claim 128, wherein the surfactant is DPPC.

130. (Previously Presented) A method of claim 73, wherein at least 10% of the therapeutic polysaccharide is delivered to the blood within one hour.

131. (Previously Presented) The method of claim 73, wherein at least 20% of the therapeutic polysaccharide is delivered to the blood within one hour.

132. (Previously Presented) The method of claim 73, wherein at least 40% of the therapeutic polysaccharide is delivered to the blood within one hour.

133. (Previously Presented) The method of claim 73, wherein at least 50% of the therapeutic polysaccharide is delivered to the blood within one hour.

134. (Previously Presented) A method of claim 73, wherein at least 10% of the therapeutic polysaccharide is detectable in the blood within one hour.

135. (Previously Presented) The composition of claim 82, wherein the particles are spherical.

136. (Previously Presented) The composition of claim 82, wherein the particles are non-spherical.

137. (Previously Presented) The composition of claim 82, wherein the particles are porous.

138. (Previously Presented) The composition of claim 82, wherein the particles are non-porous.

139. (Previously Presented) The composition of claim 82, further comprising a surfactant.

140-157. (Canceled)

158. (Previously Presented) The method of claim 59, wherein dry aerosol containing a therapeutic polysaccharide is administered in an effective amount to produce the peak concentration or activity of therapeutic polysaccharide within one and one half hours.

159. (Previously Presented) The method of claim 59, wherein dry aerosol containing a therapeutic polysaccharide is administered in an effective amount to produce the peak concentration or activity of therapeutic polysaccharide within one hour.

160. (Previously Presented) The method of claim 59, wherein dry aerosol containing a therapeutic polysaccharide is administered in an effective amount to produce the peak concentration or activity of therapeutic polysaccharide within one half hour.

161. (Canceled)

162. (Currently Amended) The method of claim [[161]] 59, wherein the heparin-like glycosaminoglycan is ~~selected from the group consisting of~~ a low-molecular-weight heparin, heparin, ~~or heparin sulfate, biotechnology derived heparin, chemically modified heparin, heparin analogue, and unfractionated heparin preparation.~~

163. (Previously Presented) The method of claim 59, wherein the dry aerosol contains an unformulated dry polysaccharide.

164. (Previously Presented) The method of claim 59, wherein the dry aerosol contains a dry polysaccharide formulated in a surfactant.

165. (Previously Presented) The method of claim 164, wherein the surfactant is DPPC.

166. (Previously Presented) The method of claim 164, wherein the surfactant is coated on the particle surface.

167. (Previously Presented) The method of claim 164, wherein the surfactant is incorporated into the formulation.

168. (Currently Amended) The method of claim 59, further comprising administering an additional therapeutic agent.

169. (Previously Presented) The method of claim 168, wherein the additional therapeutic agent is selected from the group consisting of proteins, peptides, nucleic acids, and small organic molecules.

170. (Previously Presented) The method of claim 59, wherein the dry aerosol containing a polysaccharide includes both a formulated and an unformulated dry polysaccharide.

171-175. (Canceled)

176. (Previously Presented) The method of 79, wherein the dry aerosol is administered in an effective amount for producing a therapeutic effect within 15 minutes of administration.

177. (Previously Presented) The method of 79, wherein the dry aerosol is administered in an effective amount for producing a therapeutic effect within 10 minutes of administration.

178-184. (Canceled)

185. (Currently Amended) The kit of claim [[184]] 91, wherein the heparin-like glycosaminoglycan is selected from the group consisting of a low-molecular-weight heparin, heparin, or heparin sulfate, ~~biotechnology derived heparin, chemically modified heparin, heparin analogue and unfractionated heparin preparation.~~

186. (Previously Presented) The kit of claim 91, wherein the mean geometric diameter of the particles is between 1 and 500 μm .

187. (Previously Presented) The kit of claim 91, wherein the mean geometric diameter of the particles is between 1 and 106 μm .

188. (Previously Presented) The kit of claim 91, wherein the mean geometric diameter of the particles is between 5 and 53 μm .

189. (Previously Presented) The kit of claim 91, wherein the aerodynamic diameter of the particles is between 1 and 5 μm .

190. (Previously Presented) The kit of claim 91, wherein the aerodynamic diameter of the particles is selected from the group consisting of 5-35 and 35-75 microns..

191. (Previously Presented) The method of claim 99, wherein the ratio of unformulated preparation to formulated preparation is 90:10.

192. (Previously Presented) The method of claim 99, wherein the ratio of unformulated preparation to formulated preparation is 70:30.

193. (Previously Presented) The method of claim 99, wherein the ratio of unformulated preparation to formulated preparation is 50:50.

194. (Previously Presented) The method of claim 99, wherein the ratio of unformulated preparation to formulated preparation is 30:70.

195. (Previously Presented) The method of claim 99, wherein the ratio of unformulated preparation to formulated preparation is 10:90.

196. (Currently Amended) The method of claim 99, wherein the polysaccharide glycosaminoglycan is a glycosaminoglycan selected from the group consisting of a heparin, a heparin sulfate, or a low molecular weight heparin, a biotechnology derived heparin, a chemically modified heparin, a heparin analogue, and an unfractionated heparin preparation.

197. (Previously Presented) The method of claim 196, wherein the glycosaminoglycan of the formulated dry glycosaminoglycan preparation is the same as the glycosaminoglycan of the unformulated dry glycosaminoglycan preparation.

198. (Previously Presented) The method of claim 196, wherein the glycosaminoglycan of the formulated dry glycosaminoglycan preparation is different than the glycosaminoglycan of the unformulated dry glycosaminoglycan preparation.

199. (Canceled)

200. (Currently Amended) The method of claim [[199]] 99, wherein the polymer is selected from the group consisting of formulated dry glycosaminoglycan preparation includes PLA, PGA, and or PLGA.

201. (Previously Presented) The method of claim 99, wherein the formulated dry glycosaminoglycan preparation includes a surfactant.

202. (Previously Presented) The method of claim 201, wherein the surfactant is DPPC.

203. (Previously Presented) The method of claim 99, wherein the relative ratio of formulated to unformulated preparation is selected from the group consisting of 10:90, 20:80, 30:70, 40:60, 50:50, 60:40, 70:30, 80:20, and 90:10.

204. (Previously Presented) An unformulated dry glycosaminoglycan having a mean geometric diameter of 10-500 microns.

205. (Previously Presented) A method for delivering a glycosaminoglycan to a subject, comprising, administering to a pulmonary tissue of a subject the glycosaminoglycan of claim 204.

206. (Previously Presented) The unformulated dry glycosaminoglycan of claim 204, wherein the unformulated dry glycosaminoglycan has a mean geometric diameter of 10-250 microns.

207. (Previously Presented) The unformulated dry glycosaminoglycan of claim 204, wherein the unformulated dry glycosaminoglycan has a mean geometric diameter of 10-100 microns.

208. (Previously Presented) The unformulated dry glycosaminoglycan of claim 204, wherein the unformulated dry glycosaminoglycan has a mean geometric diameter of 100-200 microns.

209. (Previously Presented) The unformulated dry glycosaminoglycan of claim 204, wherein the unformulated dry glycosaminoglycan has a mean geometric diameter of 100-150 microns.

210. (Previously Presented) The unformulated dry glycosaminoglycan of claim 204, wherein the unformulated dry glycosaminoglycan has a mean geometric diameter of 53-106 microns.

211. (Previously Presented) The unformulated dry glycosaminoglycan of claim 204, wherein the unformulated dry glycosaminoglycan has a mean geometric diameter of 20-53 microns.

212. (Previously Presented) The unformulated dry glycosaminoglycan of claim 204, wherein the unformulated dry glycosaminoglycan has a mean geometric diameter of 53-75 microns.

213. (Previously Presented) The unformulated dry glycosaminoglycan of claim 204, wherein the unformulated dry glycosaminoglycan has a mean geometric diameter of 75-106 microns.

214. (Currently Amended) The unformulated dry glycosaminoglycan of claim 204, wherein the glycosaminoglycan is ~~selected from the group consisting of~~ a heparin, a heparin sulfate, or a low molecular weight heparin, ~~a biotechnology derived heparin, a chemically modified heparin, a heparin analogue, and an unfractionated heparin preparation.~~

215. (Previously Presented) A composition, comprising:
the unformulated dry glycosaminoglycan of claim 204 and a formulated dry glycosaminoglycan preparation.

216. (Currently Amended) The composition of claim 215, wherein the glycosaminoglycan of the formulated dry glycosaminoglycan preparation is ~~selected from the group consisting of~~ a heparin, a heparin sulfate, or a low molecular weight heparin, ~~a biotechnology derived heparin, a chemically modified heparin, a heparin analogue, and an unfractionated heparin preparation.~~

217. (Previously Presented) The composition of claim 215, wherein the glycosaminoglycan of the formulated dry glycosaminoglycan preparation is the same as the glycosaminoglycan of the unformulated dry glycosaminoglycan preparation.

218. (Previously Presented) The composition of claim 215, wherein the glycosaminoglycan of the formulated dry glycosaminoglycan preparation is different than the glycosaminoglycan of the unformulated dry glycosaminoglycan preparation.

219. (Canceled)

220. (Currently Amended) The composition of claim [[219]] 215, wherein the polymer is ~~selected from the group consisting of~~ formulated dry glycosaminoglycan preparation includes PLA, PGA, and or PLGA.

221. (Previously Presented) The composition of claim 215, wherein the formulated dry glycosaminoglycan preparation includes a surfactant.

222. (Previously Presented) The composition of claim 221, wherein the surfactant is DPPC.